REMARKS

Reconsideration is respectfully requested.

On entry of this amendment, claims 1, 10-12, and 21 are amended. Claims 2-6 and 19-20 are reiterated. Claims 7-9 and 13-18 are cancelled. Claims 1-6, 10-12, and 19-21 are pending.

Amendment and cancellation of certain claims is in no way an admission of or acquiescence to the Examiner's rejection and is not to be construed as a dedication to the public of any of the subject matter of the claims as previously presented. No new matter has been added.

Applicants expressly reserve the right to pursue identical or similar claims in a continuation or divisional patent application.

Withdraw of Objections and Rejections

Applicants respectfully thank the Examiner for withdrawing the objections and rejections in the previous Office Action.

Claim Rejections – 35 U.S.C. § 112, 2nd Paragraph

The Examiner has rejected claims 7-16 and 21 as indefinite under 35 U.S.C. § 112, 2nd paragraph for allegedly failing to particularly point out or distinctly claim the subject matter which applicants regard as the invention.

A. Claims 1-16 and 21

The Examiner has rejected claims 1-16 and 21 as indefinite for reciting "modified" and "derivative." The Examiner suggests maintaining the language of "modified" and deleting the language "derivative."

Claims 10-12 and 21 have been amended to recite a "modified kringle 5 peptide" as suggested by the Examiner. The amendment merely makes explicit what was already implicit in the claims.

Claims 7-9 and 13-16 have been cancelled.

This ground for rejection is now moot. Applicants respectfully request that it be withdrawn.

B. Claims 11-12

The Examiner has rejected claims 11-12 as indefinite for lacking antecedent basis for the recitation of the term "peptide" when referencing independent claim 10.

Applicants have amended claim 10 to recite "a modified kringle 5 peptide comprising a kringle 5 peptide." Claims 11 and 12 both recite "the modified kringle 5 peptide of claim 10, wherein said kringle 5 peptide is selected from ...". (Emphasis added). As used in claims 11 and 12, "modified kringle 5 peptide" and "kringle 5 peptide" both have antecedent basis with respect to claim 10.

This ground for rejection is therefore moot. Applicants respectfully request that this ground for rejection be withdrawn.

C. Claims 14-16

The Examiner has rejected claims 14-16 as indefinite.

Claims 14-16 have been cancelled. This ground for rejection is therefore moot. Applicants respectfully request that it be withdrawn.

Claim Rejections – 35 U.S.C. § 112, 1st Paragraph, Enablement

The Examiner has rejected claims 7-16 as allegedly not enabled.

Claims 7-16

Claims 7-9 and 13-16 have been cancelled.

Claims 10-12 are directed to modified kringle 5 peptides. Claim 10 recites "a modified kringle 5 peptide comprising a kringle 5 peptide and a maleimido group which reacts with a thiol group on human serum albumin to form a covalent bond."

Claims 11 and 12 depend from claim 10.

The Examiner's Rejection

The Examiner states that "the specification, while being enabling for a composition comprising a modified kringle 5 peptide, does not reasonably provide enablement for the intended use whereby the composition is used for *in vivo* treatment of angiogenesis in humans." The

Examiner then discusses the enablement requirement as applied to *in vivo* treatment of angiogenesis in humans.

The Examiner's Rejection Distinguished

Without admitting or acquiescencing to the Examiner's rejection, Applicants have cancelled claims 7-9 and 13-16. This ground for rejection is therefore moot with respect to these claims.

With respect to claims 10-12, the Examiner has failed to establish the requisite *prima facie* ground for lack of enablement. The Examiner states that the Specification does not provide enablement for an "intended use whereby the composition is used for *in vivo* treatment of angiogenesis in humans." Claims 10-12, however, lack any such requirement. Independent claim 10 is directed to "a modified kringle 5 peptide comprising a kringle 5 peptide and a maleimido group which reacts with a thiol group on human serum albumin to form a covalent bond." Nowhere does claim 10 state that the claimed modified kringle 5 peptide is "for use for *in vivo* treatment of angiogenesis in humans." Claims 11 and 12, which depend from claim 10, also lack any such requirement.

Moreover, the Examiner admits that the Specification enables the subject matter of claims 10-12. Specifically, the Examiner states that "the specification ...[is] enabling for a composition comprising a modified kringle 5 peptide." Claims 10-12 are directed to the exact composition that the Examiner states is enabled, namely "a modified kringle 5 peptide." The Examiner has failed to establish a *prima facie* case for lack of enablement with respect to claims 10-12.

Since the Examiner has failed to establish the requisite *prima facie* basis for lack of enablement of pending claims 10-12, Applicants respectfully request that this ground for rejection be withdrawn.

Claim Rejections – 35 U.S.C. § 112, 1st Paragraph, Written Description

A. Rejection of Claims 7-16 and 21

The Examiner has rejected claims 7-16 and 21 as allegedly failing to comply with the written description requirement.

Claims 7-16 and 21

Claims 7-9 and 13-16 have been cancelled.

Claims 10-12 are directed to modified kringle 5 peptides. Claim 10 recites "a modified kringle 5 peptide comprising a kringle 5 peptide and a maleimido group which reacts with a thiol group on human serum albumin to form a covalent bond." Claims 11 and 12 depend from claim 10.

Claim 21 recites "A modified kringle 5 peptide selected from the group consisting of" as series of modified kringle 5 peptides.

The Examiner's Rejection

The Examiner states that "a review of the language of the claim indicates that these claims are drawn to a genus, i.e. the genus of derivatives of a kringle 5 peptide." The Examiner further states that "a description of a genus may be achieved by means of a recitation of a representative number of species falling within the scope of the genus or of a recitation of structural features common to the members of the genus." In addition, the Examiner asserts that "one of skill in the art would not recognize from the disclosure that the applicant was in possession of the genus of derivatives of modified kringle 5 peptides or derivatives of non-modified kringle 5 peptides."

The Examiner's Rejection Distinguished

Without admitting or acquiescing to the Examiner's rejection, Applicants have cancelled claims 7-9 and 13-16. With respect to the cancelled claims, this ground for rejection is therefore moot.

To the extent that the Examiner has rejected the claims over the term "derivative," Applicants have amended claims 10-12 and 21 to recite a "modified kringle 5 peptide." The amendment merely makes explicit what was already implicit in the claims.

With respect to amended claims 10-12 and 21, the Examiner has failed to meet the *prima facie* requirements for rejection for lack of written description. Claims 10-12 and 21 are each directed to "modified kringle 5 peptides." Applicants have provided extensive written description of numerous kringle 5 peptides, and their common structural features, as required by the Examiner. Specifically, Applicants describe kringle 5 peptides as peptides of mammalian plasminogen from page 8, line 14, through page 9, line 9. Applicants also describe numerous specific kringle 5

peptides from page 9, line 9 through page 10, line 10. SEQ ID NO: 2 through SEQ ID NO: 16 are sequences of kringle 5 peptides. Applicants teach kringle 5 peptide synthesis from page 17, line 18 through page 24, line 21, and Examples 1-5 detail synthesis of various kringle 5 peptides.

Applicants have also provided an extensive written description of modified kringle 5 peptides. Applicants describe modified kringle 5 peptides from page 10 line 19 through page 17 line 16, and page 24, line 23 through page 34, line 7. Applicants provide further disclosure of administration of a modified kringle 5 peptide from page 34, line 9 through page 35, line 32. Examples 6-25 detail the synthesis of modified kringle 5 peptides.

Because Applicants have thus provided an extensive written description of the claims, including "a representative number of species falling within the scope of the genus" of kringle 5 peptides and modified kringle 5 peptides as required by the Examiner, the Examiner has failed to provide a *prima facie* case for lack of written description of pending claims 10-12 and 21.

Applicants respectfully request that this ground for rejection be withdrawn.

B. Rejection of Claims 1-16 and 19-21

The Examiner has rejected claims 1-16 and 19-21 as allegedly failing to comply with the written description requirement.

Claims 1-16 and 19-21

Claim 1 recites "a modified antiangiogenic peptide comprising a peptide corresponding to a region of mammalian plasminogen, a reactive group which reacts with amino groups, hydroxyl groups, or thiol groups on blood components to form stable covalent bonds wherein said reactive group is selected from the group consisting of succinimidyl and maleimido groups." Claims 2-6 depend from claim 1.

Claims 10-12 are directed to modified kringle 5 peptides. Claim 10 recites "a modified kringle 5 peptide comprising a kringle 5 peptide and a maleimido group which reacts with a thiol group on human serum albumin to form a covalent bond." Claims 11 and 12 depend from claim 10.

Claims 19, 20, and 21 each recite "a modified kringle 5 peptide selected from the group consisting of" a series of modified kringle 5 peptides.

Claims 7-9 and 13-16 have been cancelled.

The Examiner's Rejection

The Examiner states that "a review of the language of the claim indicates that these claims are drawn to a genus, i.e. the genus of modified antiangiogenic peptides and compositions comprised thereof." The Examiner further states that "an adequate written description ...requires precise definition, such as by structure, formula, chemical name, or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." The Examiner admits that "one or two species may provide an adequate written description of a genus when the species disclosed are representative of the genus." The Examiner then alleges that "the specification discloses only kringle 5 peptides with claimed antiangiogenic activity, and does not disclose any other modified antiangiogenic peptides or compositions thereof."

The Examiner's Rejection Distinguished

The Examiner has failed to make a *prima facie* case for lack of written description under 35 U.S.C. §112 for the claims as amended.

With regard to claim 1 and claims depending therefrom, Applicants have amended claim 1 to recite "a modified antiangiogenic peptide comprising a peptide corresponding to a region of mammalian plasminogen, a reactive group which reacts with amino groups, hydroxyl groups, or thiol groups on blood components to form stable covalent bonds wherein said reactive group is selected from the group consisting of succinimidyl and maleimido groups." (Emphasis added). In the application as-filed, Applicants have provided written description support for a region of mammalian plasminogen. In particular, at page 8, lines 22-24, Applicants disclose that "the amino acid sequence of a complete mammalian plasminogen molecule (the human plasminogen molecule), including its kringle 5 region, is presented in (SEQ ID NO: 1)." At page 8, lines 15-22, Applicants disclose that the kringle 5 peptide is one region of mammalian plasminogen. Further, at page 1, lines 26-28, Applicants disclose that "much research has been performed to identify anti-antiangiogenic molecules," and "one antiangiogenic molecule of particular interest is plasminogen." At page 1, lines 28-32, Applicants further state "of particular interest are is the kringle 5 region of plasminogen and various peptides within the kringle 5 region. Both plasminogen and the kringle 5 region of plasminogen have been shown to interfere with the angiogenic process are thus known as

antiangiogenic peptides." Based on this disclosure, one of skill in the art would conclude that Applicants have possession of the peptides corresponding to a region of plasminogen, in satisfaction of the written description requirement.

With regard to the rejection of amended claims 10-12 and 19-21, the Examiner's rejection is entirely baseless. Claims 10-12 and 19-21 are directed to modified kringle 5 peptides, not modified antiangiogenic peptides, as alleged by the Examiner. Claims 10-12 and 19-21 all recite "a modified kringle 5 peptide." As discussed above, the specification discloses numerous kringle 5 peptides. Moreover, as the Examiner admits, that "the specification discloses structures and amino acid formulas for modified kringle 5 peptides." The rejection of claims 10-12 and 19-21 under 35 U.S.C. §112 for lack of written description is therefore improper.

Without admitting or acquiescing to the Examiner's rejection, Applicants have cancelled claims 7-9 and 13-16. This ground for rejection is now moot with respect to these claims.

In light of the above, the Examiner has failed to satisfy the *prima facie* requirements for a written description rejection of pending claims 1-6, 10-12, and 19-21, as amended. Applicants respectfully request that this ground for rejection be withdrawn.

Conclusion

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, Applicant(s) petition(s) for any required relief including extensions of time and authorizes the Assistant Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing docket no. **500862001400**.

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Respectfully submitted,

By _____

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